

NEFTEL  
Appl. No. 10/501,394  
April 9, 2008

**AMENDMENTS TO THE DRAWINGS**

In accordance with the Examiner's request, attached are replacement sheets of the drawings that incorporate the helpful suggestions of the Examiner.

Attachment: Replacement Sheet(s)

**REMARKS**

With the entry of the foregoing amendments, claims 1-24 are pending in the application. Favorable consideration is requested.

In line with the helpful suggestions of the Examiner, the drawings have been amended as set forth in the attached Replacement Sheets. No new matter has been added.

In line with the suggestions of the Examiner, the Abstract has been amended. Again, no new matter has been added.

In response to the objection to claim 10, claim 10 has been amended in order to adopt the helpful suggestions of the Examiner. Claim 1 has also been amended to place the claim in more conventional U.S. patent claim format. No new matter has been added by the amendments.

Applicant submits that the claim amendments, drawing amendments and Abstract amendments render moot the objections concerning those portions of the application.

The following prior art rejections have been lodged against the claims:

1. Claims 1-6, 8-9, 12, 14 and 17-23 stand rejected as allegedly being anticipated by Dadson (U.S. Patent 6228047).
2. Claims 7, 10 and 11 stand rejected as allegedly being obvious over Dadson in view of Klein (U.S. Patent 4244787).
3. Claims 13 and 16 stand rejected as allegedly being obvious over Dadson in view of Suzuki (U.S. Patent 6595948).
4. Claims 15 and 24 stand rejected as allegedly being obvious over Dadson in view of Skeggs (U.S. Patent 2797149).

Applicant respectfully traverses the prior art rejections for at least the following reasons.

At the outset, applicant notes that the Dadson reference is a family member of International Application No. WO 99/06082, a copy of which has already been submitted to the USPTO. Both the U.S. patent and the International application have the same or similar content. The WO reference was identified by the International Bureau during the PCT phase. The IPER, which was very positive, thoroughly discussed the WO reference. Applicant attaches a copy of the IPER hereto and is submitting a copy of the IPER with a separate Information Disclosure Statement.

In the IPER, the examiner correctly stated that “the subject matter of claim 1 differs from [the WO reference, i.e., the Dadson reference] in that the automatic peritoneal sampling system comprises MULTIPLE sampling containers and the series of valves are used to fill each of these containers” (emphasis added). Thus, the examiner determined that claim 1 was novel. The same is true in this U.S. patent application because it concerns the same claim features and the same cited Dadson reference/disclosure.

In addition, as noted in the IPER, the examiner stated that claim 1 was not obvious because “the differentiating features mentioned above have the purpose of automatically preparing and storing separate samples of dialysate liquid for later analysis. None of the available prior art documents describes the physical storing of a plurality of dialysate liquid samples for later use, neither before nor after each sample has been analyzed.” These statements are absolutely correct and confirm that the claimed invention is not obvious in view of Dadson either alone or in any “reasonably apparent” combination with any other known prior art. As stated by the Supreme Court in *KSR*, there must be a “reasonably apparent” way to combine references that would yield the claimed invention. In this case, the primary reference, Dadson, fails to disclose or suggest the foregoing claimed features, and the secondary references do not

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overcome those deficiencies because they also lack any disclosure or teaching of the foregoing claimed features. Thus, the claimed invention is patentable over any of the cited references either individually or in any "reasonably apparent" combination. Accordingly, applicant requests the withdrawal of the prior art rejections.

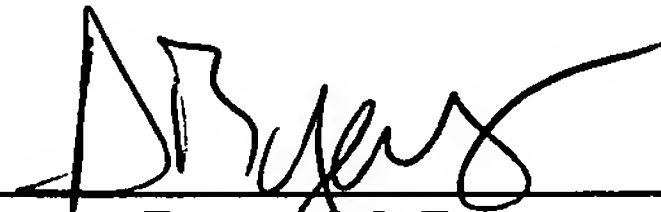
In view of the foregoing amendments and remarks, applicant submits that this application is in condition for allowance. A notice to that effect is earnestly solicited.

If the Examiner has any questions concerning this case, the undersigned may be contacted at 703-816-4009.

Respectfully submitted,

**NIXON & VANDERHYE P.C.**

By: \_\_\_\_\_



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# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 0147-007.B.WO	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/CH 03/00048	International filing date (day/month/year) 23.01.2003	Priority date (day/month/year) 28.01.2002
International Patent Classification (IPC) or both national classification and IPC A61M1/28		
Applicant DEBIOTECH S.A. ET AL.		
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p><input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of 4 sheets.</p>		
<p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> <li>I <input checked="" type="checkbox"/> Basis of the opinion</li> <li>II <input type="checkbox"/> Priority</li> <li>III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</li> <li>IV <input type="checkbox"/> Lack of unity of invention</li> <li>V <input checked="" type="checkbox"/> Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</li> <li>VI <input type="checkbox"/> Certain documents cited</li> <li>VII <input type="checkbox"/> Certain defects in the international application</li> <li>VIII <input type="checkbox"/> Certain observations on the international application</li> </ul>		
Date of submission of the demand  25.08.2003	Date of completion of this report  16.04.2004	
Name and mailing address of the international preliminary examining authority:   European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer  Kroeders, M  Telephone No. +31 70 340-1967  	

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. **PCT/CH 03/00048**

**I. Basis of the report**

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

**Description, Pages**

1-8 as originally filed

**Claims, Numbers**

1-24 received on 16.03.2004 with letter of 16.03.2004

**Drawings, Sheets**

1/2-2/2 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
  - ☐ the language of publication of the international application (under Rule 48.3(b)).
  - ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:
- ☐ contained in the international application in written form.
  - ☐ filed together with the international application in computer readable form.
  - ☐ furnished subsequently to this Authority in written form.
  - ☐ furnished subsequently to this Authority in computer readable form.
  - ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
  - ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.
4. The amendments have resulted in the cancellation of:
- ☐ the description, pages:
  - ☐ the claims, Nos.:
  - ☐ the drawings, sheets:

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/CH 03/00048

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Yes: Claims	1-24
	No: Claims	-
Inventive step (IS)	Yes: Claims	1-24
	No: Claims	-
Industrial applicability (IA)	Yes: Claims	1-24
	No: Claims	-

2. Citations and explanations

**see separate sheet**

**Re Item V**

**Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

Document WO-A-9906082, which is considered to represent the most relevant state of the art, discloses (cf. page 6, line 19 to page 16, line 7):

automatic peritoneal dialysis sampling system (14, 30) adapted to automatically sample at specific time intervals volumetric fractions of dialysate contained in the peritoneum of a patient in order to improve the peritoneal dialysis for a given patient, wherein the peritoneal dialysis sampling system (14, 30) comprises a sampling container (30) and pumping means (P1) disclosed in combination with a series of valves (14, belonging to an automated peritoneal dialysis system) adapted to direct a certain quantity of fluid from a series of containers (S1, S2, G1, M1, M2) to a patient

The subject-matter of claim 1 differs from this disclosure in that the automatic peritoneal sampling system comprises multiple sampling containers and the series of valves are used to fill each of these containers.

In view of said difference, the subject-matter of claim 1 is new and meets the requirements of Article 33(2) PCT.

The differentiating features mentioned above have the purpose of automatically preparing and storing separate samples of dialysate liquid for later analysis.

None of the available prior art documents describes the physical storing of a plurality of dialysate liquid samples for later use, neither before nor after each sample has been analysed.

Therefore, the subject-matter of claim 1 involves an inventive step and the claim meets the requirements of Article 33(3) PCT.



**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

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International application No. PCT/CH03/00048

The automatic peritoneal sampling system disclosed in claim 1 is industrial applicable and therefore the requirements of Article 33(4) PCT are met as well.

Claims 2 to 24 depend from claim 1 and refer to further embodiments of the automatic peritoneal sampling system described in claim 1 or a peritoneal dialysis system containing the automatic peritoneal sampling system of claim 1. Thus, claims 2 to 24 meet the requirements of Articles 33(2), (3) and (4) PCT for the same reasons explained above.